DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 17, 2014

Avantis Medical Systems, Inc.
Louis Fries
Consultant, Regulatory Affairs
263 Santa Ana Court
Sunnyvale, CA 97085-4511

Re: K140595
Trade/Device Name: Third Eye Panoramic Auxiliary Endoscopy System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDF, FDS
Dated: October 3, 2014
Received: October 6, 2014

Dear Louis Fries,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 3

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K140595

Device Name: Third Eye® Panoramic™ Auxiliary Endoscopy System

Indications for Use: The Avantis Medical Systems, Inc. Third Eye Panoramic Auxiliary Endoscopy System is indicated for use as an accessory to a conventional colonoscope to provide additional visualization and illumination of the colon for diagnostic purposes.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) SUMMARY

a) Applicant Information:

Date Summary Prepared	17 November 2014
Sponsor/Submitter	Avantis Medical Systems, Inc. 263 Santa Ana Court Sunnyvale, CA 94085-4511
Correspondent Contact Information	Louis Fries Consultant Regulatory Affairs Phone: 510-862-2034 Fax: 408-733-1847 E-mail: lfries@avantismedical.com Salmaan Hameed Vice President Research and Development Phone: 408-826-9740 Fax: 408-733-1847 E-mail: shameed@avantismedical.com

b) Device Information:

Device Common Name	Endoscope
Device Trade & Proprietary Name	Third Eye® Panoramic™ Auxiliary Endoscopy System (Third Eye)
Device Classification Name	Endoscope & Accessories (per 21CFR 876.1500)
Device Classification Regulation	21CFR 876.1500
Device Classification	Class II (special controls)
Device Classification & Product Code	FDF, FDS

c) Identification of Predicate Device:

The Avantis Third Eye Panoramic Device (Panoramic Device) is substantially equivalent in operation and fundamental scientific technology to its previous version, the Retroscope, cleared under K070330, K083180, K091783 and K093187.

d) Device Description Summary:

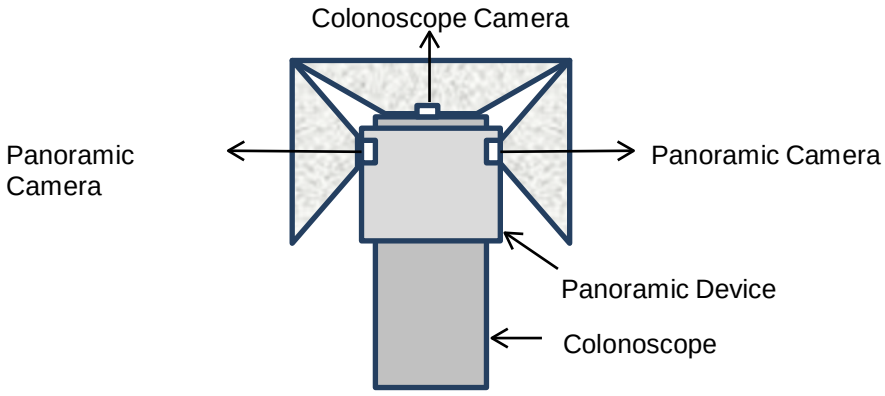
Third Eye Panoramic Auxiliary Endoscopy System consists of two main portions:

1. Disposable device components packaged and supplied together as a single-use sterilized unit.
   a. The Panoramic Device: (catheter with cameras and LED light sources at the distal end and connection to video processors at the proximal end)
   b. Attached Water Module to rinse the camera lenses: (catheter with water rinse sprayer distal end and connection to water source at the proximal end)

2. Facility Equipment: The non-disposable facility equipment portions of the device include two Third Eye Video Processors and cables (No change from predicate except for a minor label change).

Description

The Panoramic Device is designed as an accessory device for use with a standard colonoscope to provide lateral and partial retrograde visualization and illumination of the colon during a colonoscopy procedure. Prior to insertion of a standard colonoscope, the Panoramic Device (including the Water Module) is attached to the distal end of the colonoscope with a flexible clip. The Panoramic Device travels with the colonoscope and provides continuous left-side and right-side views of the colon that supplement the forward view of the colonoscope. The images from the colonoscope and the Panoramic Device are displayed simultaneously on three separate monitors, providing a panoramic image with a total angle of view of approximately 310° as shown schematically below.



The Third Eye Video Processor was previously cleared under 510(k) K070330, K083180, K091783, and K093187 is unchanged for the purposes of this submission except for a minor labeling change (removal of the word “Retroscope” to allow for use with both the Retroscope and the Panoramic devices).

e) Intended Use:

The Avantis Medical Systems, Inc. Third Eye Panoramic Auxiliary Endoscopy System is indicated for use as an accessory to a conventional colonoscope to provide additional visualization and illumination of the colon for diagnostic purposes.

f) Substantial Equivalence:

The **Panoramic Device** (the subject of this 510(k)) and the predicate **Retroscope** are both indicated for use with a colonoscope to provide visualization and illumination of the colon for diagnostic purposes using video camera(s).

The Panoramic Device is indicated for the same use as the predicate device except it utilizes two cameras oriented laterally on the left and right sides of the device with angles of view that are sufficient to allow examination of the colonic mucosa in the lateral and backward directions.

The predicate Retroscope is inserted through the channel of the colonoscope after the colonoscope has been advanced to the cecum. The Retroscope cannot be used during the intubation phase and must be removed from the colonoscope channel every time a snare or forceps is inserted through the channel to perform a polypectomy or biopsy.

Like the Retroscope, the Panoramic Device is inserted into the colon for viewing visualization and illumination. However, the Panoramic Device is attached externally to the distal end of the colonoscope rather than passing through the colonoscope’s instrument channel like the Retroscope.

The Panoramic Device reduces the complexity of the set up and simplifies operability compared to the Retroscope.

Since the colonoscope channel remains unobstructed, this configuration allows the Panoramic Device to be used during both the intubation and withdrawal phases of the colonoscopy procedure and it can remain in place even when the endoscopist is performing biopsies or polypectomies.

The Panoramic Device is constructed of the same materials as the predicate Retroscope with the addition of a new medical grade epoxy adhesive. The Panoramic Device utilizes the same camera, LED light source, and Video Processor as the Retroscope. Because the Panoramic Device utilizes two cameras, a second, identical video processor is required.

The Panoramic Device's left and right-lateral views, complementing the forward view of the colonoscope, may assist the endoscopist in determining the most appropriate direction to deflect the colonoscope's tip during intubation without excessive pressure against the wall of the colon, which may reduce patient discomfort and lower the risk of perforation of the colon.

The Panoramic Device is substantially equivalent to the cleared predicate (Retroscope) in fundamental design, materials of construction, manufacturing processes, packaging (including sterile barrier packaging) and sterilization. All changes have been subjected to risk analysis and have been verified to meet current design specifications.

g) Scientific Technology

The Third Eye Panoramic Auxiliary Endoscopy System includes the Panoramic Device containing two cameras and two LED light sources, an attached Water Module, and two Video Processors. Modifications made to the device and accessories did not change the fundamental scientific technology of the device which is to provide additional visualization and illumination of the colon during colonoscopy. The testing described demonstrates that the proposed Third Eye Panoramic Auxiliary Endoscopy System does not raise any new or unresolved issues for safety and efficacy.

h) Summary of Supporting Non-Clinical Performance Data

No animal testing was performed. Bench verification testing was conducted to verify that the modified device meets the design inputs and intended performance requirements. Results demonstrate that the modified Third Eye Panoramic Auxiliary Endoscopy System performs as intended.

i) Summary of Supporting Clinical Feasibility Data

Results from a feasibility study conducted at New York Hospital Queens Medical Center support performance and operability of the device. Results for the initial 17 subjects indicate that presence of the Third Eye Panoramic Device did not interfere with any of the functions of the colonoscope and that the side-viewing cameras were useful for detecting lesions that were not found in the colonoscope's forward view. See Section 7.